AUG 1 5 2001

K012348

BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Regulatory Specialist

Proprietary Name: Maxim® RPG PS Femoral Component

Common or Usual Name: femoral knee component

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (CFR 888.3560)

Device Classification: Class II

Device Product Code: 888.3560

Legally Marketed Device to which Substantial Equivalence is Claimed: Maxim® PS Femoral Component

Device Description:

The Maxim® RPG PS Femoral Components are composed of Co-Cr-Mo. The posterior stabilized femoral components provide posterior femoral rollback via a femoral cam that articulates with a polyethylene post on the tibial component. The minor modifications made were to the trochlear groove, and PS Box.

There are three sizes available in both right and left configurations for the Maxim® RPG PS Femoral Components. The anatomic component design allows the surgeon to reconstruct the anatomic dimensions and kinematics of the natural femur.

Intended Use:

The Maxim® RPG PS Femoral Component is indicated for:

1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where on or more compartments are involved.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended for use with bone cement.

Summary of Technologies: In terms of overall design, including geometry, materials, and fixation enhancements, as well as intended use, the Maxim® RPG PS Femoral Component is equivalent to the predicate device. Minor changes were made to the predicate femoral component.

Non-Clinical Testing: Mechanical analysis was completed to determine substantial equivalence.

Clinical Testing: Clinical testing was not used to determine substantial equivalence.

Maxim® is a registered trademark of Biomet,Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K012348
Trade Name: Maxim® RPG PS Femoral Component
Regulation Number: 888.3560
Regulatory Class: II
Product Code: JWH
Dated: July 7, 2000
Received: August 4, 2000

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012348

Device Name: Maxim® RPG PS Femoral Component

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1) Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2) Correction of varus, valgus, or posttraumatic deformity.
3) Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OF ANOTHER PAGE IS NEEDED)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012348